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INVENTOR(S)					
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<input type="checkbox"/> Additional inventors are being named on the ____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
VASCULAR FILTER WITH IMPROVED STRENGTH AND FLEXIBILITY					
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Respectfully submitted,

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Date 09/19/02

REGISTRATION NO.
(if appropriate)
Docket Number:

39,564

BES 0009 MA

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This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicants : Petrus A. Besselink
 Title : VASCULAR FILTER WITH IMPROVED STRENGTH AND FLEXIBILITY
 Docket No. : BES 0009 MA

BOX PROVISIONAL PATENT APPLICATION


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BES 0009 MA

Vascular filter with improved strength and flexibility

Abstract:

This invention relates to membranes for vascular filters with improved strength and flexibility compared to the filters that are now on the market. The filters make use of a proximal frame section and a distal section, made of a flexible thin membrane with perfusion holes of a diameter that allows blood to pass, but prevents the movement of emboli downstream. Both can be collapsed into a small diameter delivery catheter and expanded upon release from this catheter. The distal filter membrane has a proximal entrance mouth, which has almost the same size as the body lumen. It is attached to the proximal section, which has the function to keep the mouth of the distal filter open and prevent the passing of emboli between the body lumen wall and the edge of the filter mouth. In order to have a good flexibility the membrane is made extremely thin. Normally this would create the risk that the membrane could tear easily, which could cause big problems because emboli and pieces of the membrane would then be taken downstream from the filter site. This problem is overcome by embedding the filter membrane with thin filaments of a material with high strength in longitudinal direction, but high flexibility upon bending. Such a composite filter membrane can have extreme flexibility and elasticity in certain directions, combined with limited deformation, high strength and prevention of crack propagation through the membrane material. Further the filaments can be attached to the proximal frame in such a way that the connection points act as hinges and as additional safety for the case that the membrane material might come loose from the frame. Another function of the embedded filaments is that they help to give the membrane a desired shape after deployment. A method for producing such filters is also disclosed. The reinforced membranes can also be used for parts of catheters, like for example inflatable parts, balloon pumps, replacement of body tissues, repair of body parts and functional parts like artificial valves and membranes.

Background of the invention

This application relates to the field of producing an expandable frame with a membrane that is placed in a body lumen, like for example an improved distal filter for protection against emboli, which can migrate during angioplasty/stenting procedures.

In US 5,885,258 a retrieval basket for catching small particles was disclosed, made from a slotted nitinol tube. The pattern of the slots allows expansion of the nitinol basket and by shape setting (heat treatment in the desired unconstrained geometry) this basket is made expandable and collapsible by means of moving it out or into a surrounding delivery tube.

In principle a distal filter is made of such an expandable frame that defines the shape and enables placement and removal, plus a filter membrane or mesh that does the actual filtering work.

Sometimes the expandable frame and the mesh are integrated and made from a single material, for example Nitinol, like in US 6,383,205 or US 2002/0095173. These filters do not have a well-defined and constant size of the holes where the blood flows through, because of the relative movement of the filaments in the mesh. This is a disadvantage, because the size of emboli can be very critical, e.g. in procedures in the carotid arteries. Further the removal of

such a filter, accompanied by a reduction of the diameter, may be critical because emboli can be squeezed through the mesh openings with their changing geometry.

A much better control of the particle size is achieved with a separate membrane or filter sheath, which has a well-defined hole pattern with for example holes of 100 microns, attached to a frame that takes care of the correct placement and removal of the filter. In WO 00/67668 a Nitinol basket forms the framework of the filter, and a separate polymer sheath is attached around this frame. At the proximal side the sheath has large entrance ports for the blood and at the distal side a series of small holes filters out the emboli. This system, however, has some major disadvantages. First of all, the closed basket construction makes this filter frame rather rigid and therefore it is difficult to be used in strongly tortuous arteries. In a curve it may even not fit well against the artery wall and cause leakage along the outside of the filter. Another disadvantage of such filters is there is a high risk of squeezing-out the caught debris upon removal, because the struts of the framework force the debris back in proximal direction, while the volume of the basket frame decreases when the filter is collapsed. Further the construction makes it very difficult to reduce the profile upon placement of the filter. This is very critical, because these filters have to be advanced through critical areas in the artery, where angioplasty and/or stenting are necessary. Of course the catheter that holds this filter should be as small as possible then. In the just described filter the miniaturization will be difficult, because at a given cross section there is too much material. The metal frame is surrounded by polymer and in the center there is also a guide wire.

In US 6,348,062 the frame is placed proximal and the distal polymer filter membrane has the shape of a bag, attached to one or more frame loops, forming an entrance mouth for the distal filter bag. Here the bag is made of a very flexible polymer and the hole size is well defined. Upon removal the frame is closed, thus closing the mouth of the bag and partly preventing the squeezing-out of debris. This is already much better than for the full basket design, which was described above, where the storage capacity for debris of the collapsed basket is relatively small. The filter bag is attached to the frame at its proximal end and sometimes to a guide wire at its distal end. Attachment to the guide wire can be advantageous, because some pulling force may prevent bunching of the bag in the delivery catheter. It may be clear that it is easier to pull a flexible folded bag through a small diameter hole, than to push it through. However, the deformation of the bag material should stay within certain limits, and it would be excellent if these limits would be controllable. If the filter is brought into a delivery sheath of small diameter, collapsing the frame and pulling the bag into the delivery sheath causes rather high forces on the connection sites of filter to frame and/or guide wire. While the metal parts of the frame slide easily through such a delivery sheath, the membrane material may have the tendency to stick and in the worst case it may even detach from the frame, tear upon placement or during use, just because of too much friction, unlimited expansion, crack propagation etc. The connection of the filter bag to the frame is rather rigid, because of the method of direct attachment. Additional flexibility, combined with a high strength attachment spot would also be advantageous. To overcome the strength problem, the membrane may be made thicker, but this makes the overall size also larger and thus the crossing profile. If the membrane is relatively thick, the blood flow through the holes will of course also be less than in the case where the holes are made in an extremely thin membrane.

Methods for making kink resistant reinforced catheters by embedding wire ribbons are described in PCT/US93/01310. A mandrel is coated with a thin layer of encapsulating material. Then a means (e.g. a wire) for reinforcement is deposited around the encapsulating

material and eventually a next layer of encapsulating material is coated over the previous layers, including the reinforcement means. Finally the mandrel is removed from the core of the catheter. Materials for encapsulating are selected from the group consisting of polyesterurethane, polyetherurethane, aliphatic polyurethane, polyimide, polyetherimide, polycarbonate, polysiloxane, hydrophilic polyurethane, polyvinyls, latex and hydroxyethylmethacrylate. Materials for the reinforcement wire are stainless steel, MP35, Nitinol, tungsten, platinum, kevlar, nylon, polyester and acrylic. Kevlar is a Dupont product, made of long molecular highly oriented chains, produced from poly-paraphenylene terephthalamide. It is well known for its high tensile strength and modulus of elasticity.

In US 09/537,461 the use of polyethylene with improved tensile properties is described. It is stated that high tenacity, high modulus yarns are used in medical implants and prosthetic devices. Properties and production methods for polyethylene yarns are disclosed.

US 5,578,374 describes very low creep, ultra high modulus, low shrink, high tenacity polyolefin fibers having good strength retention at high temperatures and methods to produce such fibers. In an example the production of a poststretched braid, applied in particularly woven fabrics is described.

In US 2001 0034197 oriented fibers are used for reinforcing an endless belt, comprising a woven or non-woven fabric coated with a suitable polymer of a low hardness polyurethane membrane, in this case to make an endless belt for polishing silicon wafers. Examples are mentioned of suitable yarns like meta- or para-aramids such as KEVLAR, NOMEX OR TWARON; PBO or its derivatives; polyetherimide; polyimide; polyetherketone; PEEK; gel-spun UHMW polyethylene (such as DYNEEMA or SPECTRA); or polybenzimidazole; or other yarns commonly used in high-performance fabrics such as those for making aerospace parts. Mixtures or blends of any two or more yarns may be used, as may glass fibres (preferably sized), carbon or ceramic yarns including basalt or other rock fibres, or mixtures of such mineral fibres with synthetic polymer yarns. Any of the above yarns may be blended with organic yarns such as cotton.

Disclosure of reinforcement of thin membranes with fibers for the use in filters is not found in the known literature.

Summary of the invention

This invention relates to vascular filters with improved strength and flexibility compared to the filters that are now on the market. The filters make use of a proximal and a distal section, which can be collapsed into a small diameter delivery catheter and expanded upon release from this catheter. The proximal section is made as a frame of a relatively rigid material, for example a metal and the distal section is made of a flexible thin membrane with perfusion holes of a diameter that allows blood to pass, but prevents the movement of emboli downstream. The distal filter membrane has a proximal entrance mouth, which has almost the same size as the body lumen. It is attached to the proximal section, which has the function to keep the mouth of the distal filter open and prevent the passing of emboli between the body lumen wall and the edge of the filter mouth. In order to have a good flexibility and a minimized crossing profile upon delivery the membrane is made extremely thin. Normally this would create the risk that the membrane could tear easily, which could cause big problems because emboli and pieces of the membrane would then be taken downstream from

the filter site. This problem is overcome by embedding the filter membrane with thin filaments of a material with high strength in longitudinal direction, but high flexibility upon bending. Such a composite filter membrane can have extreme flexibility and elasticity in certain directions, combined with limited deformation, high strength and prevention of crack propagation through the membrane material. Further the filaments can be attached to the proximal frame in such a way that the connection points act as hinges and as additional safety for the case that the membrane material might come loose from the frame. Another function of the embedded filaments is that they help to give the membrane a desired shape after deployment. The surface of the membrane filter may be coated with some additional material that improves the properties, for example the biocompatibility, drugs release or any other desired property, which the membrane itself does not offer. Another object of the invention is that the reinforced membranes can also be used for parts of catheters, replacement of body tissues, repair of body parts and functional parts like artificial valves and membranes, where minimal thickness and/or high strength are required.

Detailed description of the invention

The advantages of the invention will become more apparent after reference to the following description, wherein some embodiments are elucidated.

In the present invention a filter with improved flexibility and smaller profile is described. The filter basically has a proximal frame for expansion and contraction and attached thereto a thin filter bag which basically exists out of minimal two materials. One material is the highly flexible filter membrane itself, with a pattern of holes for allowing flow of blood particles below a well defined size, and the other material is a reinforcement made of fine fibers with high axial strength but thin enough to be flexible upon bending. The reinforcement is integrated with the membrane to create a composite structure with very flexible membrane areas where the blood is filtered and extremely strong reinforcement fibers that take up excessive forces, control the shape of the filter and act as flexible hinges at the points of attachment to the proximal frame and/or the guide wire. These fibers can be embedded in the membrane by a dipping or spraying process or they can be attached with glue, stitching, a solvent for the membrane material, heat, welding etc. In order to get a better connection between the reinforcement fibers and the membrane material the fibers may first be coated with a material that adheres well to the membrane material, for example with the same material. Fibers can be made of any strong and tough material, preferably a material with a modulus of elasticity that is much higher than for the surrounding membrane. It can be made of round, flat or different shaped mono-filaments or multi-filaments and it can be based on metal, for example titanium or Nitinol, carbon, boron, glass, or polymers, for example ultra high molecular weight polymers with extreme tensile strength and high modulus. The fibers not only reinforce the membrane, but also can be used to control the final geometry, stop crack propagation, act as hinges at the place of attachment to the frame and prevent loss of the membrane or parts of it. Because of the reinforcement the membrane itself can be made much thinner, so the crossing profile of the composite filter can be much lower than for a single polymer membrane, even if the reinforcement fibers are much thicker than the membrane itself.

A method for making such a reinforced filter is also disclosed. A paraffin mold is prepared into the desired shape of the filter bag and then it is provided with a polymer skin, which easily detaches from the membrane polymer. This paraffin mold is dipped in a solution of polymer and solvent until a layer of membrane polymer is created. After that step the mold is

attached to the frame and the coated reinforcement fibers are then mounted to the frame at the hinge sites and laid over the surface of the mold. Another dipping step then ensures full embedding of the fibers into the growing membrane polymer layer. Finally the hole pattern is laser drilled into the membrane and the last step is the removal of the paraffin by melting it out in warm water. The polymer skin easily detaches from the inside of the filter membrane and is pulled out. With the use of a paraffin mold it is possible to make complicated or very simple designs, because there is no need to remove a relatively large mandrel from the filter after it has been made. This would be complicated if the mandrel was for example a metal or polymer part, which had to be pulled through some openings at the proximal side.

Description of the drawings

The principles of the disclosed invention become clear in the following description of the figures. Identical parts in different figures are mentioned with the same number.

Figure 1 shows a paraffin mold 1, made in the desired filter shape. Paraffin is chosen, because it can be removed from the filter easily, at a temperature that does not cause degradation of the polyurethane of the filter. However, dipping of polyurethane directly to the paraffin is not giving good results and a thin layer of polyvinylalcohol 2 surrounds therefore this paraffin mold. The polyvinylalcohol is a thin sheet that can be stretched after wetting with water and pulled tight around the paraffin and then tied together with a small clip or wire 3. Then it is dipped a few times in a solution of polyurethane in tetrahydrofuran, thus building a layer of polyurethane of e.g. 3 microns at the right side of the dipping line.

Figure 2 gives a nitinol frame 20, made from tubing with outer diameter 0.8 mm by laser cutting and shape setting. At the proximal side, which is on the left, the tube end 25 is uncut and still 0.8 mm. in diameter. From there eight longitudinal spokes 26 run until they end in a zigzag section with struts 27, where the unconstrained, expanded diameter is 8 mm at its largest size. This frame 20 will, at any size between the maximum diameter and the collapsed size of 0.8mm diameter, always adapt smoothly to the given geometry of the artery. In this frame the mold of figure 1 is placed and eight wires of a reinforcement fiber 28 of for example multifilament ultra high molecular weight polymer are attached to the most distal section of the nitinol frame 20 at points 29. These fibers can be attached to the nitinol by means of a knot or they can just be wrapped around the nitinol struts and run back and forth from the distal tip to the strut ends 29. At the distal tip all fibers come together in a guide ring or tube 30, where they are held in correct position for the further dipping.

Figure 3 shows how the mold with the nitinol frame and the surrounding fibers have been dipped a few more times until the fibers are well embedded in the polyurethane, for example until the layer polyurethane is 5 microns thick at the places 31 where no reinforcement fibers 28 are. Of course the thickness at the places 32, where these fibers are, is larger than at places 31, dependent of the type of fibers and the amount of dipping steps. Guide tube 30 of figure 2 has been removed after the dipping was finished and the membrane was dry.

Figure 4 shows the final filter 40, with a pattern of holes 41 of 100 micron diameter, which has been laser drilled between the reinforcement fibers 28 and after that the central paraffin mold has been removed by melting in warm water of 50 degrees celsius. The polyvinylalcohol layer easily released from the polyurethane filter membrane and was removed. Further the fibers 28 have been cut to the correct length at point 42 and attached to the central guide wire 43 in a nose tip 44 that fits on top of the delivery catheter if the filter is

withdrawn into this catheter before placement into the body lumen of the patient. Note that the polyurethane between the nitinol struts was also removed at the proximal side of the struts 27, preferably by laser cutting.

This construction is extremely strong and still very flexible. The 5 microns thick membrane with the reinforcement fibers 28 fits easily in a delivery catheter of only 0.9 mm inner diameter and adapts to all sizes of arteries between 1 and 8 mm diameter. The central guide wire 43 helps to pull the filter membrane out of the delivery catheter, and all tension force is taken up by the reinforcement fibers 28. The membrane only has to follow these fibers and unfold as soon as it leaves the catheter. The filter opens because of the elasticity of the nitinol frame and also because the blood pressure even helps it further to open like a parachute. Upon bending there is almost no force needed at the sites where fibers are attached to the nitinol struts, so these sites act as hinges. Even in strongly curved arteries the filter frame still adapts well to the wall and there is almost no blood leaking between membrane and artery wall. The fibers are so well embedded in the polyurethane, that in case the polyurethane detaches from the nitinol struts, the membrane will still have a strong connection to the frame and can be collapsed and removed from the patient safely. In case of a tear in the membrane, for example starting from a 100 micron hole, this membrane may tear further, but only until the crack meets a fiber. There the crack will stop, and the membrane can be removed safely and completely as well. (Of course this situation is very undesirable and the loss of some entrapped emboli may be the consequence, but at least the removal of the filter itself does not cause problems). After the procedure the nitinol frame can be collapsed to close the mouth of the filter and entrapped emboli can not leave this closed filter bag anymore. The hinges guarantee now that the filled bag hangs at the distal end of the removal catheter and still can move easily through curved arteries.

The reinforcement wires are not only used for their high tensile strength. Nitinol wires can be shape set to almost any desired shape by heat treatment. Such wires may be embedded in or attached to the membrane to guarantee a smooth folding/unfolding of the membrane. An example is an embedded nitinol wire that helps to give the mouth of the filter membrane a smooth geometry that fits well to the artery wall. Such a nitinol wire for shape control can be combined with a more flexible, but stronger fiber, which is used to protect the membrane against incidental overload, crack propagation or any of the described problems in non-reinforced membranes. Orientation and amount of the reinforcement fibers are not limited and vary with the application.

In figure 5 a distal filter 50 is given, with a conical shaped filter membrane 51, attached to the same proximal wire frame 20 as in figures 2- 4. In this example, however, the membrane is not dipped directly to the nitinol frame. It is attached by guiding for example the reinforcement fiber 52 from the distal end 53 under an angle with the cone surface until it reaches the nitinol struts 27 at points 29, than wrapped around these struts at points 29 and guided back to the distal tip with a reverse angle. Arrows in the drawing show how fiber 52 runs back and forth. By this method the use of knots at the fiber-nitinol connection is redundant and the safety is further increased, because the filter can never detach from the frame. The pattern with crossing reinforcement fibers gives the filter membrane different elastic properties and gives the benefit of an improved, but limited axial elasticity. The pattern of filter holes, preferably cut by laser, can be made between the fiber zones to stay away from damaging the fibers. However, if the pattern of reinforcement fibers is very fine, the holes may just be cut without looking at the position of these fibers. There will than still

be enough reinforcement left, just because adjacent crossing, parallel or angled uncut fibers can take over some forces via the embedding material of the membrane itself.

The cone design has the following advantages. If this filter has a maximum diameter of 8 mm and if it is placed in an artery of 8mm diameter, all holes will be free from the artery wall and blood can flow through all holes. As soon as particles of debris, like emboli, are entrapped, they will tend to collect at the most distal tip, leaving the more proximal holes open. The surface area of the flanges of the cone relates to the cross section area of the artery as the length of the cone edge from base to tip relates to the radius of the artery. Preferably, the accumulated surface area of the holes should be at least equal to the cross section area of the artery in order to guarantee an almost undistorted blood flow. This is the case if the relation between the total surface area of cone surface to total accumulated hole surface area is smaller than the relation between cone surface area and cross section area of the artery. For an 8mm artery a total amount of 6400 holes with 100microns diameter is needed for a same surface area. Of course the type of flow through small 100micron holes is different from the undistorted flow of an open artery. However, because the wall thickness of a reinforced membrane according to this invention can be extremely small, the length of a hole (for example only 5 microns) ensures a much better flow than compared to a 100 micron hole in a thick membrane. A filter made in conical shape will also have enough free holes if it is used in arteries with smaller diameter. The holes that touch the artery wall will not anymore contribute to the flow, but the remaining free holes still have the same surface area as the actual cross section of the (smaller) artery. Filters according to this invention are so much more flexible than existing filters, that they can be made longer without creating problems in strong curves. Therefore they can have more storage capacity for emboli.

If the reinforced membrane and the filter frame are mounted to each other without overlap, like in figure 5, it may be clear that the collapsed diameter can be made smaller than in the case of for example figure 4. Here, at a specific cross section of the nitinol frame near the attachment points 29, the nitinol, the membrane, the fibers and a central guide wire are all taking their part of the available cross section in the delivery sheath. It depends on the demands if this is allowable, or that a design is chosen without overlap, where frame and membrane are separated by the fiber hinges, thus reducing the size.

It is an object of the invention that the thickness of a membrane with improved flexibility for use in a human body is minimized by the use of a composite material, comprising a thin membrane layer and a reinforcement material to ensure that it keeps enough strength or enable a proper attachment.

It is also an object of the invention that the membrane is attached to a frame to bring and hold said reinforced membrane in the desired shape.

Another object of the invention is that the frame is used to collapse or expand the reinforced membrane.

It is further another object of the invention that the reinforced membrane contains a pattern of holes to let body fluid through, while particles above a certain critical size are not allowed to flow through.

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In yet another object of the invention the frame and reinforced membrane are used as a blood filter to prevent emboli above a given size to pass through the device, while the normal blood flow remains intact.

It is also an object of the invention that the blood filter according to this invention is used for distal protection in medical procedures comprising angioplasty and stenting.

Another object of the invention is that the reinforced filter membrane is used outside a patient's body.

Still another object of the invention is that the reinforcement fibers have a relatively high tensile stress and modulus of elasticity, compared to the material of the membrane itself.

It is further another object of the invention that the reinforcement fibers are relatively flexible upon bending.

Another object of the invention is that the reinforcement fibers have such properties that they are suitable to be used to bring and hold the membrane into a desired shape.

Of course it is also an object of the invention that reinforcement fibers of different types are used in the same product, comprising the use of fibers for shape control combined with fibers with high tensile strength.

It is an object of the invention that the reinforcement fibers can be made of a mono-filament or multi-filament and that they can have all kinds of cross sections and orientations.

It is also an object of the invention that the reinforcement wires are coated in a polymer to enhance the adhesion to the membrane material, including the coating with the same polymer.

Another object of the invention is that the coated reinforcement wires are glued to the membrane with a solvent for the given membrane material.

Another object of the invention is that the material, used for the membrane, includes but is not limited to all polymers, organic tissue and tissue from human or animal origin.

It is also an object of the invention that the membrane itself is made as a mesh.

Still another object of the invention is that the material for the reinforcement fibers includes all known materials, comprising carbon, glass, metals, metal alloys, for example nitinol, polymers, including ultra high molecular weight highly oriented polymers or combinations thereof.

It is further another object of the invention that the reinforcement wires can be attached to or in the membrane and to the frame by means of any known technique, including the use of dipping, spraying, welding, glue, stitching, sewing, pressing, heat, light and knotting.

Another object of the invention is that the reinforcement fibers are an integral part of the frame.

It is also an object of the invention that the sites of attachment of reinforcement fibers to the frame act as hinges to increase the flexibility.

It is further another object of the invention that the fibers can stop crack propagation through the membrane and prevent detachment of (parts of) the membrane.

It is an object of the invention that the fibers are distributed over the membrane surface in a specific designed pattern or in a random pattern.

It is also an object of the invention that the holes in the membrane are distributed over the membrane surface in a specific designed pattern or in a random pattern, even if they cut through the reinforcement fibers.

Another object of the invention is that the use of reinforcement fibers makes it possible to reduce the membrane thickness so much that the flow resistance through the holes in the membrane is minimized.

In yet another object of the invention the use of reinforcement fibers makes it possible to reduce the membrane thickness so much that the flow resistance through the membrane wall becomes so small, that it can act as a semi-permeable membrane.

Another object of the invention is the method that comprises preparing a mold of a material with a melting point well below the temperature where the membrane material is damaged, covering the mold with an intermediate material that allows the creation of a membrane surface on it, creating a membrane surface, providing the reinforcement fibers, covering the fibers with another layer of membrane surface, removing the mold by melting or solving and removing the covering of said intermediate material from the membrane surface.

It is further another object of the invention that the surface of the membrane filter may be coated with some additional material that improves the properties, for example the biocompatibility, drugs release or any other desired property, which the membrane itself does not offer.

It is within the scope of the invention that any material or any combination of materials can be used in any configuration to apply a pattern of reinforcement fibers to the membrane and to the frame.

Still another object of the invention is that the reinforced membranes can also be used for parts of catheters, like for example inflatable parts, balloon pumps, replacement of body tissues, repair of body parts and functional parts like artificial valves and membranes.

It will be obvious to those skilled in the art having regard to this disclosure that other modifications of this invention beyond these embodiments specifically described here may be made without departing from the spirit of the invention. Accordingly, such modifications are considered within the scope of the invention as limited solely by the appended claims.

Fig. 1

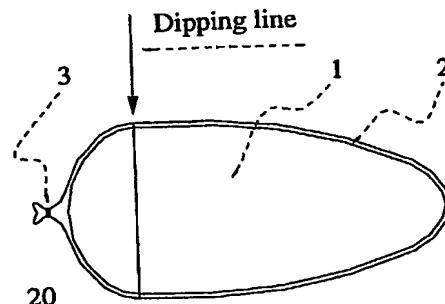


Fig. 2

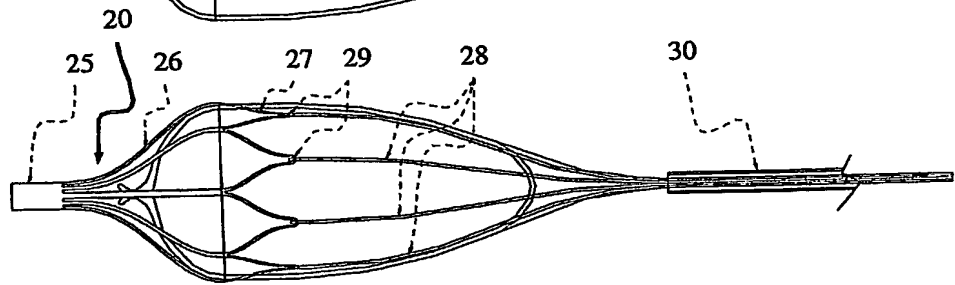


Fig. 3

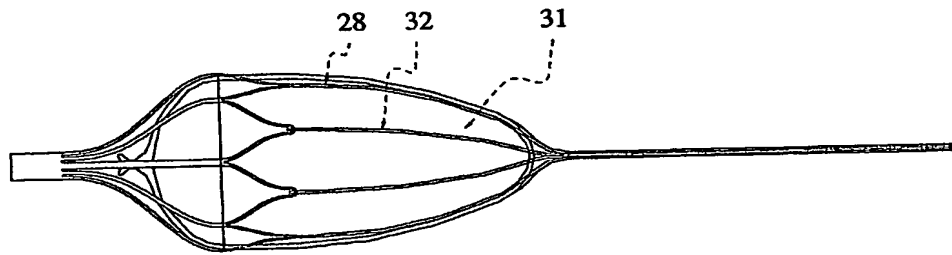


Fig. 4

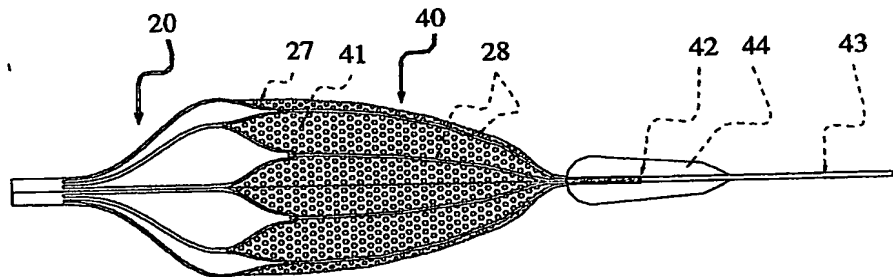
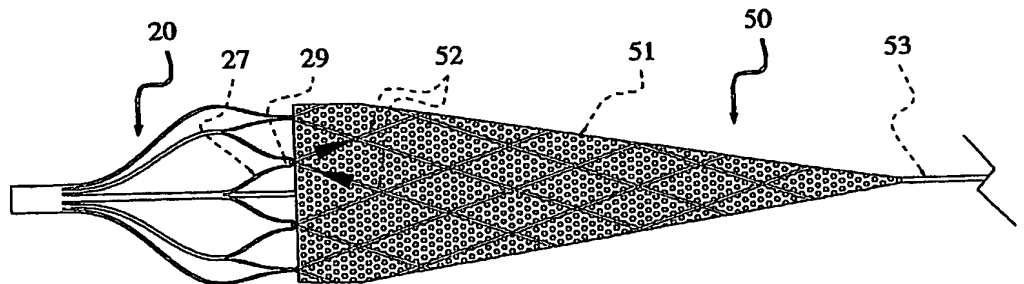


Fig. 5



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